Application No.: 10/049,192 Art Unit: 1648

### **REMARKS**

Claims 40-71 and 73-93 are pending in this application. Claims 57-59, 62, 64-71, 73-76, and 79-93 stand rejected. Claims 82-93 stand objected to. Claims 40-56, 77, and 78 are withdrawn, as they are drawn to non-elected groups/species. The Applicants herein amend the specification to update the status of all of the related applications. While the Applicants inserted a line with the cross-reference to the related applications in their transmittal form for their PCT application, they herein amend this cross-reference statement to remove reference to the two GB provisional applications. The Applicants herein cancel Claims 57-71, 73-76, and 79-81 without prejudice or disclaimer. In addition, the Applicants herein amend Claims 82-89, 92, and 93 to clarify the instantly claimed invention. The Applicants herein amend Claim 82 to replace "a guanine (G) at position 897" with "an adenine (A) at position 109. This guanine reference in Claim 82 at position 897 was a typographical error. Claim 82 is drawn to the P43 variant of VP7 in Table 3 (page 16, lines 1-4 of the specification). Table 3 indicates that the three mutations in the P43 variant of VP7 are: an adenine (A) at position 108, a thymine (T) at position 605, and an adenine (A) at position 897 from the start codon. The Applicants apologize to the Examiner for this error, which was done inadvertently and without deceptive intent. Lastly, the Applicants also herein add new Claims 94-145. Support for these amendments can be found in at pages 1-4, 16, and elsewhere in the as-filed specification, and Claims 57-71, 73-76, 82, and 84. Therefore, the Applicants introduce no new matter with these amendments.

The Applicants submit that the new and amended claims still fall within elected Group III. For the record, the Applicants respectfully disagree with the statement that their election was made without traverse. In their Preliminary Amendment and Response to Restriction Requirement filed on 29 August 2005, the Applicants elected Group III with traverse; pursuant to MPEP § 818.03(a), they pointed out the supposed errors in the restriction requirement in their response. Therefore, the Applicants submit that their election of Group III should be treated as an election with traverse.

## **CLAIM OBJECTIONS**

The Examiner objected to Claims 82-93 as being dependent upon a rejected base claim, but indicated that these claims would be allowable if rewritten into independent form. As amended, Claims 82-93 do not depend upon any of the rejected base claims. Furthermore,

Application No.: 10/049,192

Art Unit: 1648

new Claims 94-145 depend from allowed Claims 82 and 84. The Applicants note for the Examiner that they do not herein amend Claims 87, 88, and 90, because such claims are already in independent form.

### CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 57-59, 62, 64-71, 73-76, and 79-93 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Specifically, the Examiner contends that it is not clear what the phrase "a single variant or a substantially single variant" means in Claim 57 and those claims that depend from Claim 57. The Applicants herein cancel Claims 57-71, 73-76, and 79-81 without prejudice or disclaimer. However, with respect to Claims 82-89, as amended, and 90-93, Applicants respectfully traverse these grounds of rejections.

It is settled law that claim terms must be interpreted in light of the specification. The instant specification, at page 4, lines 8-11, defines the term, "variant" to mean "the nucleotide sequence encoding at least one of the major viral proteins designated as VP4 and VP7." Therefore, the variant is defined with respect to given nucleotide sequences, provided for VP4 and VP7 in the as-filed specification. Accordingly, the Applicants submit that this term does not therefore introduce any indefiniteness in these claims. Furthermore, at page 4, lines 15-17, the as-filed specification also defines "a single variant, or substantially a single variant" as "a rotavirus population which does not contain more than 10%, and preferably less than 5% and most preferably less than 1% of a different variant or variants." In other words, the as-filed specification defines the phrase "substantially single variant" as at least a 90% single variant. The Applicants submit one of skill in the art would understand the meaning of this phrase when read in light of the specification.

For all of the above reasons, the Applicants respectfully assert that Claims 82-93, as amended, as well as new Claims 94-145 are sufficiently definite. Accordingly, they request reconsideration and withdrawal of all of the grounds of rejection of Claims 82-93 under 35 U.S.C. § 112, second paragraph.

# **CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

Claims 57, 58, 69, and 79-81 stand rejected as being allegedly anticipated by Hoshino, *et al.* (US2002/0058043) under 35 U.S.C. § 102(e). In addition, Claims 57-59, 62, 65, 69, 71, 80, and 81 stand rejected as being allegedly anticipated by Burke, *et al.* (US 5,932,223). To advance the prosecution of this application, the Applicants herein cancel Claims 57, 58, 69, 73, and 79-81. Also, the Applicants note that, although new Claim 94 is

Application No.: 10/049,192 Art Unit: 1648

independent, it simply combines the limitations of allowed Claims 82 and 84. Moreover, new Claims 95-145 all depend from allowed Claims 82 and 84. Therefore, all of these rejections under 35 U.S.C. § 102 are most and should be withdrawn.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

Claims 57, 58, 69, 73, and 79-81 stand rejected under 35 U.S.C. § 103, as allegedly unpatentable over Hoshino, *et al.* in view of Chen, *et al.* (US 6,552,024). In addition, Claims 57-59, 62, 64-67, 69, 74, and 79-81 stand rejected under 35 U.S.C. § 103, as being allegedly unpatentable over Hoshino, *et al.* in view of Tsutsumi, *et al.* (US 4,152,421). Lastly, Claims 57-59, 62, 64-71, 74-76, and 79-81 stand rejected as being allegedly unpatentable over Hoshino, *et al.* in view of Tsutsumi, *et al.* (US 4,152,421), and further in view of the Therapeutic Goods Administration in the Department of Community Services and Health in Australia (1991).

As noted above, to expedite prosecution of the instant application, the Applicants herein cancel Claims 57, 58, 69, 73, and 79-81, thus rendering all of these rejections under 35 U.S.C. § 103 moot. Also, the Applicants note that, although new Claim 94 is independent, it simply combines the limitations of allowed Claims 82 and 84. Moreover, new Claims 95-145 all depend from allowed Claims 82 and 84. Therefore, all of these rejections under 35 U.S.C. § 102 are moot and should be withdrawn.

The Applicants thank the Examiner for the Office Action, and believes that this they have fully responded to the Office Action. The Applicant reserves the right to prosecute, in one or more patent applications, the cancelled claim, the claims as originally filed, and any other claim that is supported by the instant specification. In view of the foregoing amendments and remarks, the Applicant respectfully submits that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, she may contact the Applicants' undersigned attorney at the below telephone number to resolve such issues and advance this application to issue.

Respectfully submitted,

Elizabeth J. Hechtl Attorney for Applicants Registration No. 41,824

GlaxoSmithKline Corporation Corporate Intellectual Property - UW2220 P.O. Box 1539 King of Prussia, PA 19406-0939 Phone (610) 270-5009 / Facsimile (610) 270-5090